Complete Summary

GUIDELINE TITLE

Epididymitis. Sexually transmitted diseases treatment guidelines 2006.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Epididymitis. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):61-2. [222 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Epididymitis. Sexually transmitted Diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):52-3.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 08, 2008, Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.
- <u>September 11, 2007, Rocephin (ceftriaxone sodium)</u>: Roche informed healthcare professionals about revisions made to the prescribing information for Rocephin to clarify the potential risk associated with concomitant use of Rocephin with calcium or calcium-containing solutions or products.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Epididymitis

GUIDELINE CATEGORY

Diagnosis Evaluation Management Prevention Treatment

CLINICAL SPECIALTY

Family Practice Infectious Diseases Internal Medicine Preventive Medicine Urology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Managed Care Organizations
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update the Sexually Transmitted Diseases Treatment Guidelines 2002 (MMWR 2002;51[No. RR-6])
- To assist physicians and other health-care providers in preventing and treating sexually transmitted diseases (STDs)

TARGET POPULATION

Men with signs and symptoms of epididymitis

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. Evaluation of signs and symptoms (e.g., testicular pain, tenderness; hydrocele; palpable swelling of the epididymis; testicular torsion)
- 2. Radionuclide scanning of the scrotum
- 3. Color duplex Doppler ultrasonography
- 4. Gram-stain of urethral secretions demonstrating ≥5 white blood cells (WBC) per oil immersion field
- 5. Leukocyte esterase test on first-void urine
- Microscopic examination of first-void urine sediment demonstrating <u>></u>10 WBC per high power field
- 7. Culture or nucleic acid amplification test for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*
- 8. Testing for other STDs if condition is newly diagnosed

Treatment

- Ceftriaxone plus doxycycline (for epididymitis caused by gonococcal or chlamydial infection)
- 2. Ofloxacin or levofloxacin (for epididymitis caused by enteric organisms or for patients allergic to cephalosporins and/or tetracycline)
- 3. Bed rest, scrotal elevation, analgesics as adjunct therapy

Management

- 1. Follow-up for clinical improvement, reevaluation of diagnosis and therapy in case of failure to improve; differential diagnosis
- 2. Referral of sex partners for evaluation and treatment
- 3. Instructions to patients to avoid sexual intercourse until they and their sex partners are cured
- 4. Considerations for patients with HIV infection

MAJOR OUTCOMES CONSIDERED

- Microbiologic cure
- Alleviation of signs and symptoms
- Prevention of sequelae
- Prevention of transmission

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Beginning in 2004, the Centers for Disease Control and Prevention (CDC) personnel and professionals knowledgeable in the field of sexually transmitted diseases (STDs) systematically reviewed evidence (including published abstracts and peer-reviewed journal articles) concerning each of the major STDs, focusing on information that had become available since publication of the Sexually Transmitted Diseases Treatment Guidelines, 2002. Background papers were written and tables of evidence constructed summarizing the type of study (e.g., randomized controlled trial or case series), study population and setting, treatments or other interventions, outcome measures assessed, reported findings, and weaknesses and biases in study design and analysis. A draft document was developed on the basis of the reviews.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In April 2005, the Centers for Disease Control and Prevention (CDC) staff members and invited consultants assembled in Atlanta, Georgia, for a 3-day meeting to present the key questions regarding sexually transmitted disease (STD) treatment that emerged from the evidence-based reviews and the information available to answer those questions. When relevant, the questions focused on four principal outcomes of STD therapy for each individual disease: 1) microbiologic cure, 2) alleviation of signs and symptoms, 3) prevention of sequelae, and 4) prevention of transmission. Cost-effectiveness and other advantages (e.g., single-dose formulations and directly observed therapy of specific regimens) also were discussed. The consultants then assessed whether the questions identified were relevant, ranked them in order of priority, and attempted to arrive at answers using the available evidence. In addition, the

consultants evaluated the quality of evidence supporting the answers on the basis of the number, type, and quality of the studies.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse and the Centers for Disease Control and Prevention: When more than one therapeutic regimen is recommended, the sequence is alphabetized unless the choices for therapy are prioritized based on efficacy, convenience, or cost. For sexually transmitted diseases (STDs) with more than one recommended regimen, almost all regimens have similar efficacy and similar rates of intolerance or toxicity unless otherwise specified.

Acute epididymitis is a clinical syndrome consisting of pain, swelling, and inflammation of the epididymis of <6 weeks. Chronic epididymitis is characterized by a 3-month or longer history of symptoms of discomfort and/or pain in the scrotum, testicle, or epididymis that is localized on clinical examination. Chronic epididymitis has been subcategorized into inflammatory chronic epididymitis, obstructive chronic epididymitis, and chronic epididymalgia.

Among sexually active men aged <35 years, acute epididymitis is most frequently caused by *Chlamydia trachomatis* or *Neisseria gonorrhoeae*. Acute epididymitis caused by sexually transmitted enteric organisms (e.g., *Escherichia coli*) also occurs among men who are the insertive partner during anal intercourse. Sexually transmitted acute epididymitis usually is accompanied by urethritis, which frequently is asymptomatic and is usually never accompanied by bacteriuria. In men aged >35 years, sexually transmitted epididymitis is uncommon. However, bacteriuria secondary to obstructive urinary disease is relatively common. In this group, nonsexually transmitted epididymitis is associated with urinary-tract instrumentation or surgery, systemic disease, or immunosuppression.

Although the majority of patients can be treated on an outpatient basis, hospitalization should be considered when severe pain suggests other diagnoses (e.g., torsion, testicular infarction, or abscess) or when patients are febrile or might be noncompliant with an antimicrobial regimen.

Diagnostic Considerations

Men who have acute epididymitis typically have unilateral testicular pain and tenderness; hydrocele and palpable swelling of the epididymis usually are present. Although the inflammation and swelling usually begin in the tail of the epididymis, they can spread to involve the rest of the epididymis and testicle. The spermatic cord is usually tender and swollen. Testicular torsion, a surgical emergency, should be considered in all cases, but it occurs more frequently among adolescents and in men without evidence of inflammation or infection. Emergency testing for torsion might be indicated when the onset of pain is sudden, pain is severe, or the test results available during the initial examination do not support a diagnosis of urethritis or urinary-tract infection. If the diagnosis is questionable, a specialist should be consulted immediately because testicular viability might be compromised. Radionuclide scanning of the scrotum is the most accurate radiologic method of diagnosis, although it is not routinely available. Color duplex Doppler ultrasonography has a sensitivity of 70% and a specificity of 88% in diagnosing acute epididymitis.

The evaluation of men for epididymitis should include one of the following:

- Gram stain of urethral secretions demonstrating ≥5 white blood cells (WBC) per oil immersion field. The Gram stain is the preferred rapid diagnostic test for evaluating urethritis. It is highly sensitive and specific for documenting both urethritis and the presence or absence of gonococcal infection. Gonococcal infection is established by documenting the presence of WBC containing intracellular Gram-negative diplococci on urethral Gram stain.
- Positive leukocyte esterase test on first-void urine or microscopic examination of first-void urine sediment demonstrating >10 WBC per high power field.

Culture, nucleic acid hybridization tests, and nucleic acid amplification tests are available for the detection of both *N. gonorrhoeae* and *C. trachomatis*. Culture and nucleic acid hybridization tests require urethral swab specimens, whereas amplification tests can be performed on urine specimens. Because of their higher sensitivity, amplification tests are preferred for the detection of *C. trachomatis*. Depending on the risk, patients whose conditions have been diagnosed as a new STD should receive testing for other STDs.

Treatment

Empiric therapy is indicated before laboratory test results are available. The goals of treatment of acute epididymitis caused by *C. trachomatis* or *N. gonorrhoeae* are 1) microbiologic cure of infection, 2) improvement of signs and symptoms, 3) prevention of transmission to others, and 4) a decrease in potential complications (e.g., infertility or chronic pain). As an adjunct to therapy, bed rest, scrotal elevation, and analgesics are recommended until fever and local inflammation have subsided.

Recommended Regimens

For acute epididymitis most likely caused by gonococcal or chlamydial infection

• **Ceftriaxone** 250 mg IM in a single dose

PLUS

• **Doxycycline** 100 mg orally twice a day for 10 days

For acute epididymitis most likely caused by enteric organisms or for patients allergic to cephalosporins and/or tetracyclines:

• Ofloxacin 300 mg orally twice a day for 10 days

OR

Levofloxacin 500 mg orally once daily for 10 days

Follow-Up

Failure to improve within 3 days of the initiation of treatment requires reevaluation of both the diagnosis and therapy. Swelling and tenderness that persist after completion of antimicrobial therapy should be evaluated comprehensively. The differential diagnosis includes tumor, abscess, infarction, testicular cancer, tuberculosis, and fungal epididymitis.

Management of Sex Partners

Patients who have acute epididymitis, confirmed or suspected to be caused by *N. gonorrhoeae* or *C. trachomatis*, should be instructed to refer sex partners for evaluation and treatment if their contact with the index patient was within the 60 days preceding onset of the patient's symptoms.

Patients should be instructed to avoid sexual intercourse until they and their sex partners are cured (i.e., until therapy is completed and patient and partners no longer have symptoms).

Special Considerations

HIV Infection

Patients who have uncomplicated acute epididymitis and also are infected with HIV should receive the same treatment regimen as those who are HIV negative. Fungi and mycobacteria, however, are more likely to cause acute epididymitis in immunosuppressed patients than in immunocompetent patients.

CLINICAL ALGORITHM(S)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

Throughout the 2006 guideline document, the evidence used as the basis for specific recommendations is discussed briefly. More comprehensive, annotated discussions of such evidence will appear in background papers that will be published in a supplement issue of the journal *Clinical Infectious Diseases*.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis and management of epididymitis
- Prevention of transmission of gonococcal and chlamydial infection to sex partners
- Improvement of signs and symptoms (e.g., testicular pain and tenderness, hydrocele and palpable swelling)
- Decrease in potential complications of epididymitis, such as infertility and chronic pain

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These recommendations were developed in consultation with public- and private-sector professionals knowledgeable in the treatment of patients with sexually transmitted diseases (STDs). The recommendations are applicable to various patient-care settings, including family planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities.
- These recommendations are meant to serve as a source of clinical guidance: health-care providers should always consider the individual clinical circumstances of each person in the context of local disease prevalence. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in STD/human immunodeficiency virus (HIV) prevention.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Epididymitis. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):61-2. [222 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1993 (revised 2006 Aug 4)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

GUIDELINE DEVELOPER COMMENT

These guidelines for the treatment of persons who have sexually transmitted diseases (STDs) were developed by CDC after consultation with a group of

professionals knowledgeable in the field of STDs who met in Atlanta, Georgia, during April 19–21, 2005.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Epididymitis. Sexually transmitted Diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):52-3.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Workowski KA, Levine WC, Wasserheit JN. U.S. Centers for Disease Control and Prevention guidelines for the treatment of sexually transmitted diseases: an opportunity to unify clinical and public health practice. Ann Intern Med. 2002 Aug 20;137(4):255-62. Electronic copies: Available through <u>Annals of</u> Internal Medicine Online.
- The CDC Sexually Transmitted Diseases Treatment Guidelines 2004 for PDA or Palm OS. Available from the <u>CDC National Prevention Information Network</u> (NPIN) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on August 19, 2002. This summary was updated by ECRI on October 12, 2006. This summary was updated by ECRI Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs.

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